

## CASE HARDENED ORTHOPEDIC IMPLANT

### BACKGROUND

#### 1. Field of the Art

5           The present invention is related generally to metal orthopedic implant for use in joint arthroplasty. More specifically, the present invention is related to case hardened orthopedic implants.

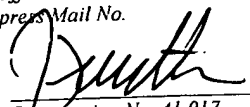
#### 2. Description of the Related Art

          Case hardening is a well known manufacturing technique that is used to surface  
10   hardened metal components. The case hardening process involves making the surface layer of a metal component harder by adding a carbon layer ("carburizing") or other materials to such surface. The surface thus becomes very hard and generally comprises higher residual compressive stresses. An advantage of case hardening a metal component is that the inner material ("core") of a case hardened device retains the mechanical  
15   properties inherent in the material, such a ductility.

          Case hardening through carburizing has traditionally been used on ferrous-based alloys. The process is also applicable to stainless steels, but not without difficulty. First, the chromium oxide surface that provides a stainless steel with its corrosion resistant properties inhibits the penetration of carbon into the surface of the stainless steel. Second,  
20   the carburization process is normally carried out at a high temperature; however, when stainless steels are carburized at high temperatures the added carbon forms chromium-carbides in the surface layer which decrease or eliminate the corrosion resistant properties of the stainless steel.

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In the field of orthopedic implant components is necessary to use biocompatible materials in the construction of prosthetic implant components. Exemplary materials include titanium alloy and cobalt chrome alloy. It is often necessary, for the various components used in a joint arthroplasty to articulate against one another. For example, the generally metal distal femoral component of a total knee arthroplasty articulates against the generally polymer bearing component that is inserted between the distal femur and proximal tibia. However, in some orthopedic joint implant designs it is desirable to have two metal components articulate against one another. In these instances, the amount of wear that the surface of such components experiences affects the longevity of the implant.

A need exists, therefore, to provide a case hardened cobalt chrome alloy or titanium alloy component.

A further need exists to provide an orthopedic implant comprising a hardened surface and an unaltered core.

A still further need exists to provide orthopedic joint implant design, wherein two case hardened metal joint components articulate against one another.

## SUMMARY

In one exemplary embodiment, the present invention comprises an orthopedic prosthetic implant component consisting essentially of cobalt chrome alloy, such that the implant comprises a core and surface layer that includes an articular surface. The surface  
5 layer is hardened by a carburization process that discourages the formation of carbides on the surface layer of the implant component.

An advantage of the present invention is that it provides biocompatible implant components having a more wear resistant articular surface, while maintaining desirable material properties such as ductility at the core of the implant component.

10 Other advantages and features of the present invention will be apparent to those skilled in the art upon a review of the appended claims and drawings.

## **BRIEF DESCRIPTION OF THE DRAWINGS**

The above-mentioned and other features and objects of this invention, and the manner of obtaining them, will become more apparent and the invention itself will be better understood by reference to the following description of an embodiment of the invention taken in conjunction with the accompanying drawings, wherein:

FIG. 1 is a cross sectional view of a femoral head implant component according to the present invention.

FIG. 2 is a cross sectional view of a femoral stem implant component according to the present invention.

FIG. 3 is a cross sectional view of an acetabular cup implant component according to the present invention.

FIG. 4 is a side elevation view of an acetabular cup implant component and a femoral head implant component according to the present invention.

Corresponding reference characters indicate corresponding parts throughout the several views. Although the drawings represent an exemplary embodiment of the present invention, the drawings are not necessarily to scale and certain features may be exaggerated to better illustrate and explain the invention. The exemplification set out herein illustrates an exemplary embodiment of the invention only and such exemplification should not be seen as limiting of the invention claimed herein.

## DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

Cobalt chrome alloy has certain material properties such as strength, ductility, biocompatibility and surface hardness that are useful in various orthopedic applications.

An example of such an application, is prosthetic implants for use with a joint arthroplasty.

5 Joint arthroplasty generally requires two or more prosthetic components to move against one another. Most orthopedic prosthetic joint designs comprise a plastic bearing component against which one or more metal components move (articulate). In some prosthetic joint designs, however, two or more all metal prosthetic joint components articulate against one another. For example, a femoral component, as shown in Fig. 1, 10 may articulate against an acetabular cup component (Fig. 3.), as shown in Fig. 4. In prosthetic joint designs, wherein one metal component articulates against another metal component it is desirable to increase the hardness of the articulating surfaces in order to increase such surfaces' resistance to wear, pitting, and other physical degradation. An advantage of such metal on metal designs is that articulating metal components, having 15 case hardened articular surfaces, last longer than traditional polymer bearing components. In a addition, the cores of case hardened metal parts are unaffected by the process thus maintaining the other material qualities of the base metal such as ductility.

The process used to harden the surface of femoral head component 10 is referred to herein as case hardening. The process comprises activating the surface (de-passivation) 20 by applying a layer of iron thereto or exposing the article surface to a hydrogen halide gas mixture of hydrogen chloride or hydrogen fluoride and nitrogen. Thereafter, the surface is carburized at a temperature and for a time insufficient for carbides to form on the surface layer. The details of the process, as it is used for various stainless steels, are described in

U.S. Patent No. 6,093,303 (the “303 patent”); the entire disclosure of which is hereby incorporated herein. The 303 patent, however, does not describe using a case hardening process on cobalt chrome alloy or on prosthetic joint components.

Referring now to Fig. 1, there is shown a cross sectional view of a femoral head  
5 implant component according to an exemplary embodiment of the present invention. The component shown can be used as a prosthetic device in a typical or minimally invasive hip arthroplasty. As shown in Fig. 1, femoral head component 10 comprises core 110, and case 100 disposed therearound. Femoral head component 10 is generally spherical, and further comprises the female portion 120 of a Morse taper style connection. Femoral  
10 head component 10 further comprises a cobalt chrome alloy material. Biocompatible cobalt alloys include: ASTM F-75, ASTM F-1537 (Alloy 1, 2, or 3), ASTM F-90, ASTM F-563, ASTM F-1058 (Grade 1, or 2), ASTM F-562, or ASTM F-799.

Referring again to Fig. 1, there is shown femoral head component 10 comprising core 110, and case 100 disposed therearound. Case 100 is a relatively thin layer on the  
15 surface of femoral head component 10 that has been case hardened to increase the surface hardness in comparison to the base metal.

Referring now to Fig. 3, there is shown a cross sectional view of an acetabular component 30 according to the present invention. Acetabular cup component 30 has a generally concave interior 300 and a convex exterior 310. Acetabular cup component 30  
20 further comprises a biocompatible cobalt chrome alloy material. The interior surface of acetabular cup component 30 is case hardened to increase the surface hardness in comparison to the base metal.

As shown in Fig. 4, femoral component 10 is placed in articular engagement with acetabular cup component 30, such that the case hardened surfaces of each component are in contact, thereby reducing the wear experienced by the case hardened surfaces, while maintaining the other physical characteristics of the base metal used to construct the implant components.

Although various embodiments of the present invention are described here and shown in the attached Figures, it is to be understood that the present invention may be used with any cobalt chrome orthopedic implant, including, by way of example but not limitation, a patellar implant, a proximal tibial implant for a knee joint, or a distal femoral implant for a knee joint. The present invention could also be used for non joint related orthopedic applications, where it is desirable to have a hard implant, such as for fracture fixation plates.